Remarks:

I. Introduction

The Applicant and Assignee would like to thank Examiner Ganesan for the courtesies she extended in the brief discussion about this application on July 23, 2008. During that call, the parties discussed the §112 rejections, the Melican application, and the Morgan patent.

Upon entry of the present amendment, claims 1-25 will be pending in this application. Claims 3-4, 12, 14, 18, and 22-23 have been amended to clarify certain aspects of the invention. Support for these amendments is discussed in detail below. No new matter has been added. Applicant submits the below remarks in an effort to move the prosecution of this application forward. It is believed that the claims as currently presented distinguish over *all* of the art of record, and Applicant respectfully requests reconsideration of the rejections and allowance of the pending claims.

Applicant also submits a revised Declaration of Commercial Success along with this response. This declaration is believed to address the deficiencies that the Examiner believed were present in the previous declaration.

II. 35 U.S.C. § 112

The Examiner has rejected claims 1-11 and 14-21 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The Examiner's position is that the specification does not support the amendment "the mesh embedded in the sheet of resin such that the resin is formed around at least a portion of the mesh, and in that portion, the resin fills the interstices of the mesh and is in contact with all surfaces of the mesh." Applicant respectfully disagrees with this rejection.

The passages from the specification cited below and the figures all show a thermoplastic resin sheet that completely surrounds the mesh, including filling the interstices of the mesh. The specification states that the metal mesh is "encased within a thermoplastic resin" (page 4, line 15); that the resin may be "formed in the interstices" of the mesh (page 5, line 32; page 6, line 13); that during manufacture, polyethylene fines "fill the void below the mesh 40, the spaces between the titanium mesh 40 and cover the top surface of the mesh 40" (page 6, lines 28-30); that "the resulting structure has titanium mesh embedded within a porous matrix" (page 7, lines 18-21); and that the mesh "is contiguous with the internal surfaces of both the top sheet 214 and the lower sheet 216" (page 10, lines 14-16).

Figure 5 shows a mold used to form the implant, and it is clear that the mesh has interstices or openings that are filled with the resin; Figure 8 is another example of a mold. Figures 11, 16, and 18 show the mesh 150, 220, 300 (respectively) embedded within the resin with the resin filling openings or interstices in the mesh.

The specification also states that "the mesh may extend from the implant structure" and that "it may be advantageous to extend the mesh from the implant structure to provide for a metal projection to be employed for the attachment of the implant during the surgical procedure." *See* specification at page 6, lines 18-21. This statement provides support for the claim language that the "resin is formed around at least a portion of the mesh," because there may be embodiments where mesh extends from the resin portion and is not embedded or encased.

During the call on July 23, the Examiner agreed that support for these claim amendments appears in at least the figures, even if the precise combination of words is not

recited in the specification. The standard for determining whether the written description requirement is met is whether the description clearly allows persons of ordinary skill in the art to recognize that the inventor invented what is claimed. *See* MPEP 2163.02, citing *In re Gosteli*, 872 F.2d 1008, 1012 (Fed. Cir. 1989). "An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, **figures**, diagrams, and formulas that fully set forth the invention." *See* MPEP 2163.02, citing *Lockwood v. American Airlines, Inc.,* 107 F.3d 1565, 1572 (Fed. Cir. 1997) (emphasis added). The subject matter of the claim need not be described literally (i.e., using the same terms) in order for the disclosure to satisfy the written description requirement.

The Examiner has the initial burden of presenting by a preponderance of the evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. *See* MPEP 2163.04. The Examiner has failed to meet that burden here. To the extent that the Examiner maintains that the specification does not support the claim amendments previously presented, Applicant respectfully requests clarification of what specific claim element(s) is/are believed to be unsupported by the application and figures as filed.

III. Specification corrections

Applicants have corrected obvious typographical and/or spelling errors in the specification, such as reference to a "sold" barrier instead of a "solid" barrier, to change "sued" to "used," and to correct the spelling of "imbedded" to "embedded."

IV. 35 U.S.C. § 103(a)

A. Melican in view of Morgan

The Examiner has rejected claims 1-11 and 14-25 under 35 U.S.C. 103(a) as being unpatentable over Melican (U.S. Pub. No. 2002/0120348) in view of Morgan (U.S. Patent No. 5,380,328). The Examiner's position is that Melican shows the claimed invention except for a metal mesh. The Examiner cites Morgan for its use of a titanium metal mesh sandwiched between polymeric sheets and submits that it would have been obvious to provide Melican with the titanium metal mesh of Morgan. Applicant respectfully traverses this rejection and requests reconsideration and withdrawal thereof. The Melican application is quite unrelated to the present application in a number of ways.

1. Melican is not bendable nor should it maintain its shape in use

First, the structure of the Melican implant is such that it is not designed to be bent or displaced by manipulation by hand, wherein upon displacement, the implant will generally maintain the shape to which it has been displaced. The Melican implant is used in applications where the surgeon *does not want* the implant to be rigid enough to maintain the shape to which it has been displaced. The Melican implant is a soft, knitted mesh that is used to repair soft tissue injury, such as injury to the pelvic floor, or to reinforce places where a tear has contributed to herniation. The implant is fixed to ***soft tissue***, which is clarified by the animal testing described in Melican example 3, in which an incision is made in the abdominal wall of a subject, sutured, and then covered with the Melican implant. *See* Melican, ¶80.

Providing a metal mesh inside the Melican implant so that the implant maintains its shape once bent, as the Examiner has suggested, would render the Melican implant unsuitable

for its intended purpose. A metal mesh embedded in the polymeric foam of Melican would provide an implant with a level of stiffness or rigidity that would cause the implant to erode the very soft tissue to which it is attached to repair. The Melican implant specifically *should not* maintain the shape to which it is bent – it should be flexible and soft so that it moves with the patient. Melican states that the reinforcing component should be made of "textiles with woven, knitted, warped knitted (i.e., lace-like), non-woven, and braided structures," (see Melican, ¶36) "bioabsorbable glass" (see Melican, ¶37), or "a thin, perforation-containing elastomeric sheet" (see Melican, ¶38). None of these materials are bendable and shapeable such that they retain their shape after bending. Nor is there any suggestion to replace the Melican reinforcement layer with any structure that retains its shape after bending.

The flexibility and softness of the Melican structure is also made clear by Melican's discussion about the tear strength of the implant – the implant should be able "to accept and retain sutures without tearing." See Melican, ¶10, 26. As background, implants used for soft tissue repair are typically so thin and delicate that they can come apart or tear during handling and use, which is why the Melican applicants explained that their implant "has sufficient structural integrity to enable it to be handled in the operating room prior to and during implantation." *See id.*

However, as discussed, embedding a metal mesh into the polymeric foam of Melican would cause the resulting implant to damage the soft tissue to which it is implanted, and such a modification would prevent it from being used as intended. Moreover, there is no teaching or suggestion in Melican that it would be necessary or even desirable to provide an implant that maintains its shape through the use of metal mesh. Put simply, there is no reason why one of

ordinary skill in the art would seek to stiffen the thin Melican sheet for use as a ***bone implant*** instead of a ***soft tissue implant***. Changing the Melican structure this way would change the entire purpose of the Melican disclosure. It is well-established that "[i]f the proposed modification or combination of the prior art would change the principle operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious." *See* MPEP 2143.02 (VI) (citing *In re Ratti*, 270 F.2d 810 CCPA 1959). A combination is not proper if it "would require a substantial reconstruction and redesign of the elements shown [in the primary reference] as well as a change in the basic principle under which the [primary reference] construction was designed to operate." *See id.* That is precisely the case here. Inserting the Morgan metal mesh into the Melican implant would be a complete redesign, and perhaps more importantly, would ruin the way that the Melican implant is designed to operate. By inserting the Morgan mesh into the Melican implant, the properties of the Melican implant that allow it to be used to repair soft tissue would be destroyed.

2. Melican is bioabsorbable

Second, the Melican application is directed to a ***bioabsorable*** implant. Both the Melican polymeric foam component and the reinforcement component are preferably bioabsorbable. Regarding the foam, Melican states that "[t]he more relevant factors in the selection of the appropriate polymer(s) that is used to form the foam component include bioabsorption" and "[t]he ability of the material substrate to resorb in a timely fashion in the body environment is critical." *See* Melican, ¶33-34. However, the claimed material to which the Melican material is being compared is not bioabsorbable. Regarding the reinforcement, Melican primarily

provides examples of biodegradable polymers. *See* Melican, ¶36-40. Providing a metal mesh embedded within the Melican implant as the Examiner has suggested would prevent the implant from being bioabsorbable, which is one of the critical features of the Melican invention. For at least the above reasons, Applicant respectfully submits that claims 1-44 and 14-21 are in condition for allowance and respectfully requests notification thereof.

Moreover, in addition to the bioabsorbability difference, the polymeric foam of Melican is also physically different from the thermoplastic resin (claim 1), and more specifically, the polyethylene (claims 7-8) and porous polyethylene matrix (claims 22-23) of the present invention. The differences in manufacture result in structural differences between the materials such that even if one were to combine a metal mesh with the Melican polymeric foam, the resulting material would not be the material of the claimed invention.

3. Neither Melican nor Morgan teach the claimed solid barrier surface

With respect to claims 3 and 4, the Examiner cites the discussion of Melican regarding a barrier layer that may be present on either or both of the top and bottom surfaces. However, the Melican barrier is not a "solid barrier" as presently recited by claims 3 and 4. Support for this amendment appears in the specification at least at pages 6-10. The specification describes that this barrier "is impervious to water and serves as a barrier" (page 7, lines 18-22) and that it is a "non-porous barrier surface that is not amenable to tissue attachment to the implant" (page 8, lines 21-23). The solid barrier is made by "sintering together polyethylene fines under heat and pressure" to cause the fines to completely fuse together (page 9, line 30 – page 10, line 1).

By contrast, the Melican "barrier" is a fabric barrier comprised of small diameter fibers that enable the surface properties, such as porosity and permeability, to be controlled. *See*

Melican, ¶60. It allows diffusion of nutrients and waste products while limiting the migration of cells into the implant. *See* Melican, ¶63. It accordingly is not a "solid barrier" as claimed.

Likewise, the Morgan patent fails to teach a solid barrier as claimed. The principle object of Morgan is to provide a microporous membrane material which selectively admits biological nutrients to the tissues at the surgical site and exclude unwanted cells. *See* Morgan, col. 2, lines 52-61. There is no teaching or suggestion in Morgan to use a solid barrier on one or more surfaces of the implant. In rejecting the barrier recited by claim 23, the Examiner cited Morgan, col. 4, lines 1-6, presumably for the statement that the microporous membrane is made of PTFE fibers "with or without a high-density polyethylene backing." It is clear from the Morgan patent, however, that this is a *support backing*, not a barrier. It is likely a grid of fibers that supports the membrane but allows it to maintain its function as selectively admitting biological nutrients. To provide Morgan with a solid barrier and completely *prevent* the passage of nutrients through the implant would destroy a very important feature of the Morgan design. The Morgan implant seeks to act as a filter, whereas the claimed barrier seeks to act as a wall. Accordingly, Morgan does not teach the claimed solid barrier.

For at least these reasons, Applicant respectfully submits that claims 3 and 4 are in condition for allowance and respectfully requests notification thereof.

4. The combination of Melican and Morgan fails to teach claim 22

Claim 22 is directed toward an implant comprising a porous polyethylene matrix and a surgical grade metal mesh embedded within the matrix such that the porous polyethylene matrix fills spaces between the mesh, with pores in the top and bottom surface that are between 20-500 microns, wherein the implant is able to be bent or displaced by manipulation by hand

such that the implant will generally maintain the shape to which it has been displaced. Support for the amendments to claim 22 appear in the specification at page 9, lines 7-14 and Fig. 18.

First, the arguments set forth above regarding Melican and Morgan also apply to claim 22. In short, claim 22 relates to an implant that is bendable and shapeable and that retains its shape upon bending, which is not provided by the combination of the Melican and Morgan references.

Additionally, Melican does not teach a porous polyethylene matrix. The Examiner refers to paragraph 50, which lists polyethylene among the various types of polymers that can be added to the foam, as support for her position. However, reviewing paragraph 50 in context (along with ¶¶46-52) makes it clear that the foam sheet itself is ***not a polyethylene matrix***; the discussion in Melican cited by the Examiner relates to the option of adding various types of solids to the polymer-solvent system that is used to make the foam in order to modify the composition of the ***resulting foam surfaces***. As the added particles settle out of solution to the bottom surface, regions will be created that have the composition of the added solids. *See* Melican ¶ 46. However, there is not a sheet of polyethylene provided, and certainly the ***entire matrix structure*** of Melican is not polyethylene as presently claimed. Paragraph 47 states that added solids constitute about 1-50 volume percent of the total volume of the particle and polymer-solvent mixture. Thus, at most, there may be one or more regions on the Melican foam surface that have a concentration of polyethylene particles, but if such particles are used (Melican provides a long list of options of which polyethylene is just one of many), the result is not a "porous polyethylene matrix" as claimed. In other words, the Melican particles may impart some additional properties to the structure, but they do not form the entire structure.

Moreover, the Melican polyethylene ***particles*** are described as between 50-500 microns (*see* Melican at ¶47), whereas claim 22 recites "***pores*** that are between 20-500 microns." These are two different concepts, but the Examiner states that Melican discloses a sheet of polyethylene with pores that are sized between 20-500 microns. That is incorrect. The size referred to by Melican is ***not a pore size, but a particle size***.

Additionally, the Morgan patent describes pores that range from 0.2 to 3.0 microns (*see* e.g., col. 4, lines 6-11), many orders of magnitude smaller than those claimed. For at least these reasons, Applicant respectfully submits that claim 22 is in condition for allowance and respectfully requests notification thereof.

5. The combination of Melican and Morgan fails to teach claim 23

Claim 23 is directed toward an implant comprising a sheet of polyethylene and a surgical grade metal mesh contained therein such that the polyethylene fills spaces between the mesh, wherein the top surface comprises a solid barrier surface of polyethylene and the bottom surface comprises porous polyethylene with pores between 20-500 microns, wherein the implant is able to be bent or displaced by manipulation by hand such that the implant will generally maintain the shape to which it has been displaced. Again, the arguments set forth above regarding Melican and Morgan also apply to claim 23. In short, claim 23 relates to an implant that is bendable and shapeable and that retains its shape upon bending, which is not provided by the combination of the Melican and Morgan references. As discussed in connection with claim 22 above, Melican also fails to teach a sheet of polyethylene, as well as the claimed pore sizes.

Moreover, also as described above in connection with claims 3 and 4, Melican and Morgan also fail to teach the claimed solid barrier.

For at least these reasons, Applicant respectfully submits that claim 23 is in condition for allowance and respectfully requests notification thereof.

B. Wellisz in view of Morgan and Cohen

The Examiner has rejected claims 12-13 under 35 U.S.C. 103(a) as being unpatentable over Wellisz (U.S. Patent No. 5,743,913) in view of Morgan, further in view of Cohen (U.S. Patent No. 6,087,553). The Examiner's position is that Wellisz shows the claimed invention except for a smooth barrier surface. The Examiner cites Morgan for its use of a barrier to preclude passage of unwanted biological cells and submits that it would have been obvious to provide Wellisz with a smooth barrier surface on one side. The Examiner further states that although Wellisz and Morgan lack the use of a mold with applied heat and pressure, Cohen teaches using heat and pressure to secure polyethylene to an implant surface, and she submits that it would have been obvious to modify the methods of Wellisz and Morgan to include the use of Cohen's mold. Applicant respectfully traverses this rejection and requests reconsideration and withdrawal thereof.

First, as discussed during the in-person interview on March 11, 2008, the Wellisz patent relates to an implant that has a ***surface coating*** of a polymer, an example of which may be polyethylene granules, deposited onto a titanium base. There is no teaching or suggestion in the Wellisz patent of an implant made by the method of placing a metallic mesh in the bottom of a mold and introducing thermoplastic fines into the mold so that they fill the bottom of the mold and the ***interstitial spaces of the mesh.*** As can be seen clearly by Figure 1 of Wellisz and

as previously discussed, there is ***not*** a polymer layer within or between the fines, the polymer is a ***surface coating only***.

Nonetheless, the Examiner submits that the Wellisz patent teaches every claimed element except for a smooth barrier surface, but submits that the Morgan patent teaches the use of a barrier. As discussed above, the Morgan barrier is not a solid barrier, as claimed. The Morgan implant has a microporous membrane that precludes passage of unwanted biological cells, but the membrane "selectively admits biological nutrients to tissues at the surgical site fixed and protected by the implant structure." Morgan, col. 2, lines 56-61. The backing referred to at col. 4, lines 1-6 is not a barrier, but a support backing.

Next, the Examiner cites Cohen for its use of heat and pressure to secure polyethylene to an implant surface. Cohen uses a compression molding process to mold plastic powder to another type of material. The method of Cohen applies heat and pressure to form a ***solid*** polymer structure, not a ***porous*** structure. Applicant's claim 12 specifically recites that the implant has an opposite "porous" surface.

Moreover, Applicant does not claim to have invented the use of heat and pressure to fuse materials together. Applicant has, however, invented a new implant having a metallic mesh embedded within a thermoplastic resin, and has also invented a method for making such an implant. Accordingly, because none of the cited references teach or describe the claimed method steps, which describe how the novel implant is made, Applicant submits that claim 12 and dependent claim 13 should be allowed.

CONCLUSION

For at least the above reasons, Applicant respectfully requests allowance of the pending claims and issuance of a patent containing these claims in due course. If there remain any additional issues to be addressed, the Examiner is invited to contact the undersigned at 404.815.6147.

Respectfully submitted,

/Kristin M. Crall 46,895/

Kristin M. Crall
Reg. No. 46,895

KILPATRICK STOCKTON LLP
1100 Peachtree Street
Suite 2800
Atlanta, Georgia, 30309-4530
404.815.6147